



November 2, 2009

Honorable Joseph Lieberman
Chairman

Senate Homeland Security and Governmental Affairs Committee

Senator Susan Collins
Ranking Member

REF: WMD Prevention and Preparedness Act of 2009 (S. 1649)

Dear Senators Lieberman and Collins:

Founded in 1848, the American Association for the Advancement of Science (AAAS) is the world's largest multi-disciplinary scientific society with over 120,000 members and 262 affiliated societies, and the publisher of the prestigious peer-reviewed journal *Science*. Since the onset of the Cold War, the Association has conducted a number of programs related to the role of science in national security issues. AAAS agrees that preventing bioterrorism incidents as well as having the ability to detect and respond to unusual biological events is critical to our national security and wellbeing. With that in mind, we respectfully submit the following comments with the interest of promoting the safe and secure conduct of science.

AAAS wants to thank the Senate Homeland Security and Governmental Affairs Committee for the opportunity to provide our comments on the WMD Prevention and Preparedness Act (S. 1649). We are pleased that the following items are incorporated in the bill:

- We support development of sensible and effective initiatives that enhance existing programs rather than simply moving functions from existing agencies to the Department of Homeland Security.
- We support engagement and consultation with academic and scientific experts, especially those in management positions of government and corporate laboratories and/or research institutions, to guide the development of new security standards and regulatory oversight of select agent research programs.
- We are pleased that the bill calls for development of common standards on which all institutions working with Tier I agents can base their security measures.
- We see benefits to creating an office that has the capability of assessing current and future technologies used for counterterrorism.
- We are pleased that the bill recognizes the importance of building the international public health workforce.

Executive Office

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Specific Comments

List of Biological Threats. The list of agents that pose security risks should be assessed as a *credible threat*, not merely one that has the *potential* for being a weapon. There may be examples where an agent is a public health risk but not a national security risk. AAAS would like to stress that laboratories, equipment, and technologies are not inherently security risks. The Select Agent Program already requires all approved facilities be added to a database kept by the Centers for Disease Control and Prevention.

Hence, AAAS recommends that: A) the government should not establish a *new* system of oversight, and safety and security procedures for “Tier I” agents, rather the oversight, safety and security procedures for Tier I agents should be done within the existing select agent system.; B) guidance on safety and security measures for each tier be described to research institutions in ways that resolve continuation of current inspection problems, such as inconsistent requirements and multiple, uncoordinated inspections; and C) the desire to know the location of all U.S. biological laboratories be weighed against the credible threat (agent-based, human, and laboratory-based), associated financial and administrative burdens, and the potential unintended consequences to other national security objectives – i.e., medical countermeasures development, risk assessment, disease surveillance, etc.

Personnel Reliability. AAAS is concerned about current policy discussions in both the executive and legislative branches of government regarding personnel reliability and how these programs will be designed and implemented. These programs should not replicate the nuclear personnel reliability programs. In the absence of evidence that such programs can identify individuals likely to misuse biology, the overall costs to science, health, and other national goals from implementing such a system appear to outweigh the assumed security benefits. The Defense Science Board, the National Science Advisory Board for Biosecurity, and the National Research Council have all recommended against creating a national, formalized Personnel Reliability Program for the life sciences community working on select agents. These groups have recommended that existing procedures be corrected to achieve current security objectives. For example, Congress should look to the National Institutes of Health which has recently developed a Biological Surety Program that relies on fostering a network and culture of responsible conduct of research and has been well-received by biological safety professionals.

Furthermore, AAAS recommends that the committee consult with administrators and laboratory managers from various research institutions on how a personnel reliability program and appeals process should be developed. We also recommend that core competencies for training be identified for appropriate personnel and standards be developed based on those competencies. These training needs should take into account competencies specific to job duty, research area and techniques used, and institutional structure and leadership. Non-governmental trade associations, like the American Biological Safety Association, may be more appropriate organizations to accredit training programs, train institutional trainers, and improve training procedures as technology or methods advance.

Costs. AAAS is concerned that the initial and ongoing costs associated with implementing security measures are disproportional to the size of institutional select agent research programs. Although no comprehensive data describing security measures and associated costs exists, several academic colleagues have provided their annual cost estimates and given us permission to provide you with these estimates. The Galveston National Lab spends about \$4 million annually, Duke University will spend \$768,145 on security measures for the 2009-2010 year (includes select agents and other agents), and the Lovelace Respiratory Research Institute estimates that its costs would increase by \$1 million for the first year and \$0.5 million for subsequent years if the standards are at the DoD level. In addition to these costs, individual institutions may expect to spend about \$50,000 per inspection, which can number between 8-9 annually. Few federal funds are directly allocated for operation and maintenance of high-containment laboratories, implementing security measures, and training personnel; thus, these costs come from general institutional funds that would otherwise be available for other activities, including research and education.

Inspections. AAAS recognizes that the bill attempts to minimize the overall number of inspections conducted at a single research institution and to increase coordination among them. It is important that Congress emphasizes to federal agencies the importance of conducting joint inspections to minimize the impact of cost and time to academic institutions, procedures for notification of inspections, coordination of inspections with the select agent program, security requirements that do not conflict with the select agent program, and ways to minimize the administrative burden for each inspection.

Repository of Biological Materials. While having a repository of reference strains could be very useful for microbial forensics, it should be recognized that biological agents used in an attack may not match the strains in the repository because those agents may have naturally changed, may not have originated from a laboratory, or may be new, previously unknown agents or strains. We recognize that the bill includes an evaluation of potential proprietary and intellectual property issues associated with requesting strains from private industry and academia. An example of this type of issue may include a public and/or private research institution developing vaccines from infectious agents may not be willing (or allowed by contract) to provide the vaccine strains to a central repository because of intellectual property concerns. AAAS is concerned that encouraging public and private institutions to contribute biological agent and toxin collections to the national bioforensics repository might result in federal repositories being over-burdened with enormous numbers of submissions that are not relevant to forensic purposes.

AAAS recommends that: A) the existing CDC repository be reviewed for its sufficiency as a reference library of harmful strains; B) the roles of the FBI, CDC, and DHS be clearly delineated to avoid any confusion following an incident; and C) the lead technical agency develop guidance for vetting new technologies and techniques in the court system.

International Biosecurity. Unlike fissile materials or chemical weapons, nearly all Tier I agents are found in the environment as human, animal, and/or plant health risks. We caution that

establishing a mechanism in statute for security exchange of Tier I agents may exacerbate existing sentiments of mistrust and intellectual property problems. In addition, expanding U.S. lab capacity internationally while requesting that developing nations consolidate their Tier I agents to secure facilities and reduce or eliminate their stocks in less secure facilities could result in mistrust and diplomatic issues. We support the use of science diplomacy (government-to-government or scientist-to-scientist) as a legitimate and useful mechanism to improve international biosecurity and transparency. We also note that the National Science Advisory Board on Biosecurity, in a highly collaborative and collegial process, has conducted extensive discussions with foreign colleagues on how biosecurity awareness can most effectively be raised among the global scientific community.

AAAS recommends that A) the benefits of secure international transfer of agents be weighed against the political issues and resultant consequences as well as public health response capabilities before inclusion in the bill; and B) fostering international biosecurity and transparency should be accomplished using science diplomacy, and building trust between the U.S. and other nations.

We thank you and your colleagues for the opportunity to provide some informal comments on this draft legislation.

Should you have any additional questions or require further information, please do not hesitate to contact Kavita Berger, Ph.D., (202-326-7027 or kberger@aaas.org) or Gerald Epstein, Ph.D., (202-326-9493 or gepstein@aaas.org).

Sincerely,



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President, Board of Directors



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Chief Executive Officer, AAAS

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